

“They prefer hidden treatment”: tuberculosis drug-taking practices and drug regulation in Karakalpakstan

*Beverley Stringer¹, Karen Lowton², Professor Mirzagalib Tillashaikhov³, Professor Nargiza Parpieva³, Dilrabo Ulmasova⁴, Philipp du Cros¹, Epcó Hasker⁵, Natasha Sergeeva⁶

¹Médecins Sans Frontières (MSF), London, UK; ²Department of Sociology, University of Sussex, London, UK, ³Republican Specialized Scientific and Practical Medical Center of Phthysiology and Pulmonology, Ministry of Health Uzbekistan, Tashkent, Uzbekistan; ⁴Ministry of Health of the Republic of Uzbekistan, Tashkent, Uzbekistan; ⁵Institute of Tropical Medicine, Antwerp, Belgium; ⁶MSF, Tashkent, Uzbekistan; *Corresponding author
Email: beverley.stringer@london.msf.org

Beverley Stringer

Médecins Sans Frontières (MSF)

10 Furnival Street

London, EC4A 1AB

UK

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Summary

Setting

The joint Médecins Sans Frontières/Ministry of Health multidrug-resistant tuberculosis (MDR-TB) programme; Karakalpakstan, Uzbekistan.

Objective

Uzbekistan has high rates of MDR-TB. We aimed to understand patients' and prescribers' attitudes to TB drug prescription, regulation, and drug-taking behaviour.

Methods

Participants (12 patients, 12 practitioners) were recruited purposively. Data were gathered qualitatively using field notes and in-depth interviews and analysed thematically.

Findings

Our analysis highlighted two main themes. First, shame and stigma were reported to increase the likelihood of self-treatment and incorrect use of TB drugs, most commonly at initial stages of illness. A health system failure to promote health information was perceived, leading to wrong diagnoses and inappropriate therapies. Motivated by shame, patients hid their condition by resorting to drug-treatment options outside the programme, compounding the risk of chaotic management and dissemination of erroneous information through lay networks. Second, positive influences on treatment were reported through patients, practitioners and peers working effectively together to deliver the correct information and support, which acted to normalise TB, reduce stigma and prevent misuse of TB drugs.

Conclusion

Effective case finding, patient support and community education strategies are essential. Patients, practitioners and peers working together can help reduce stigma and prevent misuse of TB drugs.

Introduction

Multidrug-resistant tuberculosis (MDR-TB) describes TB resistant to the two most powerful first-line TB drugs: rifampicin and isoniazid. MDR-TB is an emerging global problem, affecting an estimated 3.5% of new TB cases and 20.5% of retreatment cases.¹ Drug resistance is fuelled by many factors, including the quality of TB medications, poor adherence to treatment, ineffective treatment and retreatment regimens^{2,3} and poor hospital infection control practices. In addition, direct access to arbitrary use of TB drugs for patients through the private market has been implicated in treatment failure and development of drug resistance in high-burden countries.⁴ For instance, in Tbilisi, Georgia, TB drugs, including second-line agents used to treat MDR-TB, were widely available without prescription at pharmacies.⁵ Strategies to ensure effective drug management and supply form a major component of the World Health Organisation Stop TB Strategy.⁶ It has been concluded that policies regarding the sale and distribution of TB drugs should receive more attention in the global strategy to control drug resistance.⁷

Médecins Sans Frontières (MSF) has treated MDR-TB in collaboration with the Ministry of Health (MoH) in Karakalpakstan, Uzbekistan since 2003. Within the MoH National Tuberculosis Programme, treatment for drug-resistant (DR) TB, at least in the intensive phase, is most commonly delivered on an inpatient basis. Reportedly, all parts of Uzbekistan now have access to rapid molecular diagnostics and WHO-recommended treatment regimens. In Karakalpakstan, treatment is delivered in the community, with all cases directly managed by the MoH. MSF provides technical support to clinicians, psychosocial support, side-effect medications, laboratory co-ordination and additional logistic support including infection control, nutritional support and assistance with adherence strategies.

Uzbekistan has some of the highest reported rates of MDR-TB in the world, with 23% of new and 62% of retreatment TB cases identified as MDR.⁸ Treatment for TB outside the standard National Tuberculosis Programme is known to occur, despite a national drugs policy that prohibits the selling or use of TB drugs without prescription from a TB specialist clinician or clinic.^{9,10} We mapped all of the private and MoH-affiliated pharmacies in Karakalpakstan indicated over 400 such facilities, with evidence that in some that it was possible to

purchase drugs used to treat sensitive TB without prescription - most commonly isoniazid, rifampicin and streptomycin.

The Uzbekistan Government has acknowledged the need to improve the regulatory system for drug products and pharmaceutical activity.⁹ However, Uzbekistan already has effective regulation, both in terms of policy and practice, for narcotic and psychotropic drugs. These drugs, detailed in Government-compiled lists, can be sold only under a special licence. A monthly audit is conducted, under relevant law, of medications sold against prescriptions provided to pharmacies. The Government is currently upgrading the TB drug regulation system for quality control and state registration of drugs to meet the norms and standards of the European Union and WHO. For instance, regional branches of the National Agency for Regulation of Drug Products are being established to guarantee adequate quality control.

With the present momentum for improvement of drug regulation in Uzbekistan, there is a need for better understanding of TB drug use. With the impending availability of new drugs for TB, it is essential that appropriate policies are formulated and implemented to prevent their misuse. While there is some awareness of the challenge of TB drug regulation within the MoH and the private sector, examination of local TB drug use from patient and practitioner perspectives is critical. In particular, understanding patient and practitioner beliefs, knowledge and behaviours is crucial in revising drug regulation policies.

We conducted a qualitative study to assess current policy and practice for the regulation of TB drugs in order to understand the perceptions, behaviour and experience of patients and practitioners in Karakalpakstan related to the use of TB medication. We aimed to understand and conceptualize patients' and prescribers' attitudes to TB drug prescription, TB drug-taking behaviour and the problems of TB drug regulation in a high-burden MDR-TB context.

Methods

Research design

We used a flexible participatory technique in which data were gathered from patients and practitioners using in-depth interviews guided by topic-led questions as well as field notes. Interview questions were based on themes relevant to the study aims and a literature search of studies, laws, policies and audits related to TB drug use and the role of the private market. Following standard qualitative interview procedures, the order of questions was driven by the nature of participant answers, leading to modification of the wording of questions and the order in which they were asked during interviews. The primary investigator conducting the interviews was from outside the treatment programme.

‘Fair dealing’, which searches for and represents participants’ views as dispassionately as possible and without moral judgement, was achieved by seeking a wide range of perspectives from specialised to general practitioners within the domain of caring for people with DR-TB.¹¹ Attention to negative cases was pursued, meaning that contradictory or unexpected findings were actively sought and explored to ensure predominant themes were a true reflection of participant responses.

Setting and sample

The study was conducted in the joint MoH/MSF TB programme in 2012 in three administrative districts of Karakalpakstan: Nukus, Takhiatash and Hodjeley. Recruitment of 24 participants (12 practitioners and 12 patients) relied on a programme manager within the country. Initial identification for recruitment was contingent on the inclusion criteria: new patients, patients who had completed treatment and chronic patients were eligible. TB specialists, non-specialist doctors and pharmacists working in the MoH, for MSF or the private system were included where possible.

A snowball technique was used for recruiting practitioners and patients to increase the uptake of participants who were difficult to reach due to communication and time limitations for public engagement with the research. A project manager/gatekeeper approached participants with an information sheet that outlined the study. Three people refused to participate, due to unavailability or unwillingness (one patient, two practitioners). Another patient agreed to participate, but did not attend the appointment

and was unavailable thereafter. Purposive sampling enabled recruitment of individuals with sufficient knowledge and experience of the study topic to enable development of generalised information on processes and typical patterns of meanings. Practitioner participants were mainly physicians working in the TB sector (MSF and MoH), but also general practitioners in primary health care and one MoH pharmacist. Patient participants were all DR-TB patients who had been enrolled in the national TB programme managed by MoH, in some cases with MSF support. Although a relatively small number of participants were interviewed, data collection was stopped when no new information was being generated from additional interviews.¹²

Data collection

Informed consent was sought both before and at the time of the interview using an information sheet translated into the local language (Karakalpak) stating the purpose of the study and the voluntary nature of participation. Participants additionally gave written consent on the day of their interview. Interviews were audio recorded in a private space, usually at the health facility where the practitioner worked or where the patient currently or had previously attended. All interviews were conducted with an interpreter to translate questions and responses from English to the local language. The interpreter was briefed before and after each interview to ensure the highest quality of data extraction. All interviews lasted between 45 and 60 minutes.

Although participants were able to stop their interview at any point, no-one chose to do this. Confidentiality was assured for all participants, with names of the respondents and all data referring to them being replaced by codes (D for physician, TBS for TB Specialist, PH for Pharmacist, GP for General Practitioner, and P for patient). Electronic data were password protected.

Data analysis

From the moment data were generated during the interviews the 'thinking and theorising' of data analysis began.¹³ Data were managed initially through verbatim transcription of all

recorded conversational interviews. Silences and emotional cues (e.g. sighing, laughter) in the audio recording of the interview were noted.

Open coding of interview transcripts allowed reviewing and re-reviewing of text line by line so that the 'tagging' of words, phrases or paragraphs emerged into codes, which were constantly compared and refined revealing the experiences of the participants rather than being externally imposed.¹⁴ The first author sorted codes and categories by interconnected themes or concepts¹³ and discussed these with the second author. Codes emerged inductively; themes and categories were drawn from respondents to make 'implicit belief systems explicit in order to generate some theoretical insight'.¹⁵ The decision to perform manual rather than electronic coding was partly related to the relatively small sample size and also to the value of interacting with the data in a way that promoted continuous refinement of interpretations and deeper understanding.¹³

Participant validation involved 10% of each participant's coded interview transcript chosen at random being checked by them, to ensure that the researcher's documentation and analysis were not disputed. Researcher reflexivity and awareness of the potential for 'personal or intellectual biases' were exercised¹⁶ together with use of field notes and relevant literature.

Ethics

Ethics approval was granted by the MSF Ethics Review Board and the Bioethics Commission of the Ministry of Health of the Republic of Uzbekistan.

Results

The response rate was 86%. Participant age ranged from 22 to 60 years, with equal numbers of men and women. Table 1 describes the characteristics of participants.

We present the main findings by negative and positive influences on TB treatment. Both influences highlighted the likelihood of incorrect use of TB drugs and the potential to prevent

self-administration or poor management of TB. We illustrate our findings through participants' quotes (Boxes 1 and 2).

Negative influences on TB treatment

Negative influences encompass the factors that increased the likelihood of self-treatment, incorrect use, and chaotic management of TB drugs. Key among these influences were shame and stigma, and incorrect lay knowledge.

Shame and stigma

The shame and stigma that patients felt in having TB was a major contributor to the risk of incorrect treatment. Nearly all participants, both professional and patient, referred to these concepts as incentives for people infected with TB to seek self-treatment in order to avoid disclosing their status (Box 1, quotes 1, 2).

Feelings of shame and stigma were also found to lead to chaotic management of TB treatment by patients, general practitioners and more widely in primary care; a point stressed by patients and practitioners. Participants differentiated between self-medication of TB drugs and mismanagement of these drugs by doctors or radiologists working outside the official TB programme; however, all participants associated a lack of knowledge about effective treatment of TB with the chaotic management of patient care (Box 1, quote 3). For patients, poor management by practitioners was the predominant issue (Box 1, quote 4). Of note, where patients were already in the official treatment programme, interruption of treatment due to side effects or quality of care was not seen as a risk factor for seeking alternative TB drugs, especially where disillusionment from drug side effects was the main reason for a treatment break. Instead, the inclination at this stage was towards seeking traditional healing options such as ingestion of dog fat or remedies from traditional healers (Box 1, quote 5).

Incorrect lay knowledge

The second factor influencing patients' tendency to seek treatment outside the TB control programme involved what could be termed as incorrect lay knowledge. Information conveyed

through a neighbour, relative or lay community network during collective events such as weddings or funerals was perceived by patients as instrumental in the proliferation of incorrect advice on treatment for TB. Such information was implicated in decisions to seek treatment outside the TB programme, especially where lay networks indicated a quicker treatment solution was available (Box 1, quotes 6, 7).

Risk of self-medication was highest prior to referral or entry to the TB programme. While access to TB drugs was prevalent, common knowledge about drugs specifically used to treat tuberculosis resistant to first-line therapy was limited.

In terms of common knowledge, most patient participants demonstrated familiarity with the drugs used to treat sensitive TB as opposed to TB resistant to first-line treatment (Box 1, quote 8). Doctor and patient participants referred to the easy availability of TB drugs as a factor contributing to self-medication (Box 1, quotes 9, 10). The availability of TB drugs outside the TB programme and incorrect lay knowledge about TB treatment, coupled with shame and stigma surrounding TB, have a bearing on developing policy towards regulation of TB drugs.

Positive influences on TB treatment

Positive influences on TB treatment highlight how the correct information and support, communicated between patients, practitioners and peers working together effectively, and with strong policy support, can contribute to increasing familiarity with TB. This strengthens beliefs in the treatment as a cure, reduces stigma, and prevents misuse of TB drugs.

Knowledge and belief about successful treatment

In terms of overcoming chaotic management of treatment, all respondents suggested knowledge of successful TB treatment to be a key factor. This was noted not only in terms of understanding the association between treatment and cure from a doctor-patient perspective, but also in the context of good communication between specialists and general practitioners contributing to better management of treatment regimens for TB (Box 2, quote 1). All participants referred to entry to the TB programme as helping prevent self-medication.

Once a patient had entered the treatment programme, the availability of free drugs, perceived as high quality and giving good results, was a positive feature for all participants (Box 2, quote 2,3). Both patient and practitioner insights on the control of TB treatment described easy access to medicines and the supply of formal treatment as essential to stopping self-medication.

Other predominant ideas from patients and practitioners were associated with treatment compliance and understanding the strength of the drugs used to treat DR-TB. Ways to ease the side effects of TB drugs described by patients were presented as means of enduring treatment, indicating that peer support can increase patient awareness of the importance of completing treatment (Box 2, quote 4). Seeing positive outcomes arise through treatment completion and cure strengthened patients' belief in treatment. In particular, the relationship between knowledge, belief in treatment and communicating completion of treatment and cure was stressed. One patient highlighted the education that the programme could offer through 'seeing' the disease; for example, the value of seeing the X-ray used as part of diagnosis (Box 2, quote 5).

Health practitioner, peer, and policy support

All respondents stressed the value of communication and doctor-patient support as a safeguard against alternative hidden treatments. There was evidence that this patient-centred approach built up the necessary confidence, trust and motivation for patients to continue with appropriate treatment regimens (Box 2, quote 6). Peer support, involving sharing knowledge, experience and encouragement, was presented as valuable and part of patient solidarity. Of note, this support was not reported to have reached the home; instead the place where treatment was carried out was conceptualised as the place of sanctity for patients (Box 2, quote 7). Peer support and patients' drive to overcome the difficult treatment emerged as potentially able to normalise TB. These factors should be nurtured as key components in patient-centred care, alongside effective case finding, tailored treatment and adherence.

On the question of better administrative, institutional and legal controls over the regulation of TB drug use, political leadership toward directives for more stringent control for specific TB drugs was indicated (Box 2 quote 8).

In relation to indicators for effective treatment, the predominant ideas and majority themes found in both patient and practitioner responses showed that patients were more likely to perceive treatment as effective if they were correctly educated about the merit of TB drugs and experienced the benefits of completion of treatment. This in turn was seen to endorse the value of the TB programme. Alongside the 'test and treat' health education message, 'complete and cure' was seen as equally necessary.

Discussion

Patients reported misuse of TB drugs to be most likely at the initial stage of their sickness and treatment journey. Motivated by the shame of having TB and the inherent social stigma, patients chose to hide their condition by resorting to drug-treatment options outside the National TB Programme.¹⁷ Self-treatment appeared less likely once patients had engaged with the programme, underlining the need for a strong case-finding component in the TB treatment approach. Finding patients and initiating correct diagnosis and treatment is critical to preventing a default to self-treatment and for promoting a successful outcome. Interruption of treatment was not a risk factor for seeking alternative TB drugs, but did initiate the use of alternative traditional treatments. Chaotic management of TB care was reported to be connected to instances where the primary care practitioner was presented with cases they did not know how best to treat.

The value of a treatment programme characterised by free, accessible and supportive patient-centred care was evident as an important determinant for sustaining effective treatment. As previously reported through studies looking at patient-centred care as positive for effective treatment, our findings support focus on the patient as key to maintaining good treatment practice both for primary care doctors involved in the TB programme and patients engaged in taking effective TB treatment.¹⁸ Likewise, doctor-patient trust and support were deemed significant in preventing misuse of drugs and therefore contributed to adherence.¹⁹ In

particular, Fiscella et al established that physicians' verbal behaviour during a doctor-patient encounter was associated with trust by both practitioners and patients.²⁰

As supported by a growing body of evidence,²¹ patients saw peer support and belief in treatment as vital components of the TB programme. The next challenge is to extend this support and the positive experience of TB treatment to the home and community environments. This effort should involve targeted community sensitisation and supervised home-based treatment where indicated,^{22,23} in particular where social gatherings enable the transmission of incorrect knowledge.²⁴

Knowledge about TB and treatment should be an important component of future drug regulation strategies.²⁵ The effective dissemination of correct knowledge can catalyse change. It is apparent that poor knowledge and a sense that cure is difficult or that treatment can fail can lead to stigma and non-disclosure of infection.²⁶ Therefore, the communication of correct knowledge and understanding between patients, between patients and their doctors, and between doctors is essential for uptake and completion of effective TB treatment.²⁷

Knowledge of and access to drugs used to treat sensitive TB in the private market was confirmed as a result of pharmacy audit exercise and patient knowledge drawn from the in-depth interviews. However, drugs used predominantly to treat TB resistant to first-line drugs were not as available or as well known by patients. Political leadership is an essential consideration of the new policy development towards successful TB drug control, especially in light of new drugs in the TB treatment pipeline.²⁸ The Panel shows policy recommendations that we have drawn from our research.

Limitations

Due to some patients' experience of the benefits of treatment, the potential for them to present only a very positive account has been considered in terms of objectivity from the standpoint of cure. However, patients' potential to articulate and draw on life stories related to a general engagement with treatment was well suited to the aims of the research. While the response rate was good, it is acknowledged that participants approached may have been

those easier to access by programme staff. The reason for participant refusal was linked to time availability and general doubts about the research. Even though private practitioners were not interviewed, insights into private and public health practices were seen through the perspective of all interviewees.

Participants may give responses that they think the researcher is hoping to hear; however, for this study, the researcher was sufficiently distanced from the programme to counter this effect. The study design could be seen as offering a unique chance for participants to express their views and tell their stories to an outsider who had no responsibility in the programme. As is characteristic of qualitative research, the data cannot be generalized to the population but transferability to other research findings can apply.

Conclusions

This study was stimulated by practitioners' anecdotal evidence that misuse of TB drugs was prolific through self-medication and regimen mismanagement. Our findings highlight the risks for TB drug misuse and the opportunities for prevention and reinforce the need for political engagement with the public and private sector.

Stigma and shame and the desire for patients to seek treatment elsewhere should be addressed by inclusion of case finding and community education strategies in programming. A patient-centred treatment approach to TB achieves this aim and is thus as important as the administrative regulation of drug treatment regimens. A decentralised treatment approach with stringent controls is the best solution for TB drug regulation. As first-line TB drugs are perceived as more misused than second-line drugs, stringent regulation of these drugs is a feasible and urgent next step.

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390 **Conflicts of interest**

391 None declared.

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393 **Author contributions**

394 BS wrote the protocol, conducted the fieldwork, analysed the data and wrote the first draft
395 of the manuscript.

396 KL supported protocol, analysed data and reviewed and revised the manuscript

397 MT reviewed manuscript

398 PN reviewed manuscript

399 DU reviewed manuscript

400 PdC supported protocol design and reviewed manuscript

401 EH reviewed manuscript

402 NS supported policy analysis and reviewed the manuscript

403 All authors have seen and approved the final version of the manuscript.

404 **Table 1: Participant characteristics**

Participant characteristic	Number of participants
General practitioner (GP)	2
TB specialist (TBS)	9
Pharmacist	1
Drug-resistant TB patients	
- New patients	6
- Chronic patients	4
- Completed treatment	2

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Box 1. Negative influences: Illustrative quotes from participants

Shame, stigma and chaotic management

D1 (TBS) – 1. Then we have stigma meaning that it is a very bad form stigma means not telling others you have TB or getting treatment somewhere.

P11 – 2. There are for example people of higher social levels they don't want to go to hospitals they prefer hidden treatment when they buy drugs at pharmacies they do it secretly.

Chaotic management by practitioners and patients

D7 (TBS) – 3. I visit polyclinics and show [the general practitioners] their mistakes; they still repeat them when I next visit them. It means, that people do not feel themselves responsible.

P12 – 4. When I contacted a doctor he said I got a bit cold. This and that, it had adhered to your lungs, it is enough to take these and those injections, but I couldn't get the full treatment.

P7 – 5. People say to go to a sorceress. If they believe them they may do this or that. It easier than taking drugs, that's why they prefer that way. People always seek easier ways. That's why they stop the drugs and go to them.

Incorrect knowledge

D6 (TBS) – 6. And if we talk about those who self-medicate from pharmacy, they usually say "my neighbour had TB and I get the same treatment from them, or a relative had TB, or someone at home".

D1 (TBS) – 7. They take without prescription, because they go to some events like funerals, weddings, that time they may hear "I got cough, and tried this drug". Says he/she got tubazide [proprietary name for isoniazid], isoniazid [TB drug used in standard regimen] and advises them to others. Do you get me? They gather together during these events. They say "I have cough", "your cough is very bad", "a man in a drugstore told me, advised me, I got this and got cured".

PH 10– 8. At pharmacies? Many drugstores sell ethambutol, rifampicin is easily available, isoniazid, and I think it's only pyrazinamide which is not delivered.

D10 (TBS) – 9. Yes, yes, yes, free availability sometimes they disappear for example pharmaceutical companies don't have them sometimes it happens and it is difficult to find them in drugstores and their prices increase now they are available yes available.

D4 (TBS) – 10. Well it's up to the patient because if the patient says "I will take I will find" he may do this.

Box 2. Positive influences: Illustrative quotes from participants

Knowledge about successful treatment

D1 (TBS) – 1. We should work together with GPs... We should make it better in polyclinics and work with, umm other specialist, neurologists, with surgeons.

P5 – 2. I wake up in the morning, thank God that I am good, and recently we started adding words like “when I finish the programme I will be healthy”. We live with these thoughts, with the idea that the treatment will have good effect on us.

P11 – 3. These drugs are very good! If you take them you will be cured, I believe in their power when they told me they would treat me ...I agreed despite all the difficulties.

P5 – 4. We see the results of the quality. We are getting better thanks to these drugs. We...ummm...how to say it...I...ummm...we, women here are taking drugs together and ...ummm we talk to each other having no secrets.

P1 – 5. But I have a strong belief in these drugs, the quality, the strength; I saw a picture of my lung I got happy. I believe in the effect of these drugs.

Health practitioner, peer and policy support

D7 (TBS) – 6. A doctor should pay much attention and time to the patient; I mean patient should see that not only his family wants him to recover but doctors too. Only this kind of attitude may help get him cured ... if a doctor loses a patient’s trust, patient will not give him even a chance to treat.

P6- 7. There have been many of them having problems at home, when they don’t have peace at home, they can’t take them at home, I can easily be a friend to anyone – we take drugs together here.

D5 (TBS) – 8. To prevent this... to stop selling, we need to add...include to our work the Ministry of Health, the Cabinet of ministers, tax committee, customs, Government. If the ministry, tax committee and customs agree to join you this will be successful, fines will be enough for others to stop selling.

- Political influence should be exercised by the relevant Government Ministries and WHO for more stringent control for specific TB drugs. Engagement between the public and private sector for this purpose is essential.
- A free, patient-centred TB treatment approach is equally important for effective regulation.
- The system of drug regulation for narcotic and psychotropic drugs in Uzbekistan should be adapted for TB drugs, especially for those that are vital for the treatment of drug-resistant TB.
- Effective case finding, community education and patient support strategies should be included in programming to diminish the problem of shame and the desire for patients to seek treatment elsewhere.
- Development of training and education programmes aimed at increasing clear guidance to general health practitioners: i.e. doctors, pharmacists and radiologists.
- Inclusion of peer support within national TB programme strategies to enhance shared experience of TB treatment and cure.

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